

REMARKS

Applicants wish to thank the Examiners for the time and courtesy extended by the Examiners to Applicants' undersigned representative, during the personal interview on August 6, 2009, and the telephone interview on August 13, 2009.

Pursuant to the discussions during the Examiner Interviews, Applicants have canceled all claims and inserted new claims to more particularly point out what the Applicants regard as the present invention. Further, as requested by the Examiners, Applicants have amended the specification and are submitting herewith two publications: Journal Pharmacology and Experimental Therapeutics, 2000, Vol. 293, No. 2, pages 435-443; and Clinical Pharmacology & Therapeutics, Nov. 1998, pages 553-561.¹

As discussed during the personal Examiners' Interview, the September 26, 2007, Declaration of Frank E. Blondino, Ph.D. ("Blondino Declaration") demonstrates that zolpidem is effective when administered via oral spray, and that the onset of anti-insomnia effects is surprisingly rapid compared to administration of zolpidem via oral tablets. It is known in the art to use the Digit-Symbol Substitution Test ("DSST") as an indicator of sedation, consistent with the use of DSST as set forth in the Blondino Declaration. See, e.g., J. Pharmacology & Exp. Therap. at pages 436, 439, and 441; and Clinical Pharmacology & Therap. at pages 556-558. Moreover, these desirable effects are achieved with the claimed oral sprays without any safety issues -- AUC and Cmax are similar to the tableted doses. Thus, while at early post-dosing times, blood levels are higher in the oral spray subjects, the overall AUC and Cmax over 12-hours for the oral spray surprisingly did not exceed that of the tablet.

None of the art of record teaches or suggests use of an oral spray for treatment of insomnia. Instead, the cited art is directed to completely different uses, such as analgesics. In view of the Blondino Declaration and the lack of predictability in this art, it is believed that the claims as currently amended are novel and non-obvious. Accordingly, and as agreed during the personal and

¹ Applicants wish to point out to the Examiners that David J. Greenblatt, one of the authors of these publications, is currently on the Scientific Advisory Board of NovaDel, Inc., assignee of the present application.

follow-up telephonic interviews with the Examiners, the claims as amended are believed to be in condition for allowance.

Applicants have submitted Terminal Disclaimers concurrently herewith, thus obviating any potential double patenting issues. If the Examiner should believe that anything further should be required to place this application in even better form for allowance, she is cordially invited to telephone the undersigned attorneys for Applicants.

Dated: August 31, 2009

Respectfully submitted,

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